Professional organisation statement template

Thank you for agreeing to give us a statement on your organisation's view of the technology and the way it should be used in the NHS.

Healthcare professionals can provide a unique perspective on the technology within the context of current clinical practice which is not typically available from the published literature.

To help you in making your statement, we have provided a template. The questions are there as prompts to guide you. It is not essential that you answer all of them.

Please do not exceed the 8-page limit.

e.g.
gy? y
(

What is the expected place of the technology in current practice?

How is the condition currently treated in the NHS? Is there significant geographical variation in current practice? Are there differences of opinion between professionals as to what current practice should be? What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?

A number of alternative treatments are used, topical steroids, ultra-violet light (PUVA), Acitretin, Azathioprine, Ciclosporine.

There is little evidence to support the use of these treatments but the clinical consensus is that some patients will have a good response to some of them in an unpredictable order of effectiveness

Each of these modalities carries its own side effect profile. By and large they are significantly less expensive than Alitretinoin

Are there any subgroups of patients with the condition who have a different prognosis from the typical patient? Are there differences in the capacity of different subgroups to benefit from or to be put at risk by the technology?

The hyperkeratotic (psoriasiform) pattern of hand dermatitis is more likely to show some response to Acitretin. The same may be true of Alitretinoin.

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics? Would there be any requirements for additional professional input (for example, community care, specialist nursing, other healthcare professionals)?

Alitretinoin requires careful monitoring especially in respect of the pregnancy prevention programme for eligible female patients. It is unclear how many patients would be suitable for Alitretinoin treatment it may be possible to combine the requirements of the Pregnancy prevention programme for a number of drugs including Isotretinoin and Thalidomide.

If the technology is already available, is there variation in how it is being used in the NHS? Is it always used within its licensed indications? If not, under what circumstances does this occur?

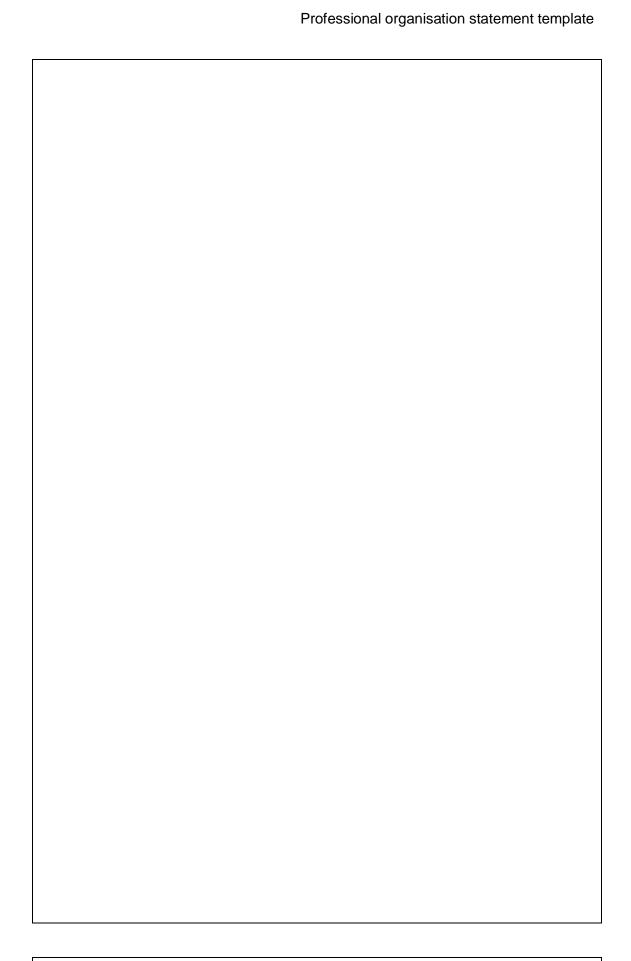
There is very little experience of Alitretinoin. Even those centres that participated in the clinical trials entered relatively few patients. It is exceedingly difficult to gauge how it will be used in future.

Please tell us about any relevant **clinical guidelines** and comment on the appropriateness of the methodology used in developing the guideline and the specific evidence that underpinned the various recommendations.

The British Contact Dermatitis Society has recently held a consensus meeting to formulate guidance for the management of hand dermatitis. These should be available by the time of the NICE STA committee meeting.

The advantages and disadvantages of the technology
NICE is particularly interested in your views on how the technology, when it becomes available, will compare with current alternatives used in the UK. Will the technology be easier or more difficult to use, and are there any practical implications (for example, concomitant treatments, other additional clinical requirements, patient acceptability/ease of use or the need for additional tests) surrounding its future use?
If appropriate, please give your view on the nature of any rules, informal or formal, for starting and stopping the use of the technology; this might include any requirements for additional testing to identify appropriate subgroups for treatment or to assess response and the potential for discontinuation.
If you are familiar with the evidence base for the technology, please comment on whether the use of the technology under clinical trial conditions reflects that observed in clinical practice. Do the circumstances in which the trials were conducted reflect current UK practice, and if not, how could the results be extrapolated to a UK setting? What, in your view, are the most important outcomes, and were they measured in the trials? If surrogate measures of outcome were used, do they adequately predict long-term outcomes?
What is the relative significance of any side effects or adverse reactions? In what ways do these affect the management of the condition and the patient's quality of life? Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently during routine clinical practice? As indicated in earlier sections the clinical experience among UK dermatologists is extremely limited. Based on the experience over many years of using Retinoid drugs for acne etc. It is likely that most patients will tolerate the medication but there is often a need to provide a significant level of support and reassurance to patients on this group of medications which have a significant side effect profile compared with many other medications in regular use.

Professional organisation statement template



Any additional sources of evidence

Can you provide information about any relevant evidence that might not be found by a technology-focused systematic review of the available trial evidence? This could be information on recent and informal unpublished evidence, or information from registries and other nationally coordinated clinical audits. Any such information must include sufficient detail to allow a judgement to be made as to the quality of the evidence and to allow potential sources of bias to be determined. There is no evidence that the BCDS is aware of beyond that which is currently being examined by NICE

Implementation issues

The NHS is required by the Department of Health and the Welsh Assembly Government to provide funding and resources for medicines and treatments that have been recommended by NICE technology appraisal guidance. This provision has to be made within 3 months from the date of publication of the guidance.

If the technology is unlikely to be available in sufficient quantity, or the staff and facilities to fulfil the general nature of the guidance cannot be put in place within 3 months, NICE may advise the Department of Health and the Welsh Assembly Government to vary this direction.

Please note that NICE cannot suggest such a variation on the basis of budgetary constraints alone.

How would possible NICE guidance on this technology affect the delivery of care for patients with this condition? Would NHS staff need extra education and training? Would any additional resources be required (for example, facilities or equipment)? Again it depends to a considerable extent on the number of patients that would meet the necessary criteria in terms of disease severity etc. While hand dermatitis can be a very significant incapacity for some patients many can have a worthwhile benefit from conventional topical therapies and improved hand protection measures. If a large proportion of difficult hand dermatitis patients were to be treated with Alitretinoin it would have a significant burden on dermatology services possibly leading to delays in treatment for other inflammatory skin disease or possibly an impact on skin cancer management. The greatest impact would be from female patients on the monthly follow-up requirement for the pregnancy prevention programme. Additional nursing and or medical resources may be needed to counter this effect.